

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 8

**Complete if Known**

Application Number	NOT YET ASSIGNED
Filing Date	ON EVEN DATE HERewith
First Named Inventor	Ramon TORRES
Group Art Unit	
Examiner Name	
Attorney Docket Number	TORRES-1B

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
SP	AA	RE 33,653		MARK et al.	07-30-1991	
	AB	4,588,585		MARK et al.	05-13-1988	
	AC	4,737,462		MARK et al.	04-12-1988	
	AD	4,904,584		SHAW	02-27-1990	
	AE	4,959,314		MARK et al.	09-25-1990	
	AF	4,965,195		NAMEN et al.	10-23-1990	
	AG	5,017,691		LEE et al.	05-21-1991	
	AH	5,116,943		KOTHS et al.	05-26-1992	
	AI	5,137,872		SEELY et al.	08-11-1992	
	AJ	5,534,617		CUNNINGHAM et al.	07-09-1996	
	AK	5,597,709		ROSEN et al.	01-28-1997	
	AL	5,612,470		THORNER et al.	05-18-1997	
	AM	5,633,352		DALBØGE et al.	05-27-1997	
	AN	5,635,604		DALBØGE et al.	06-03-1997	
	AO	5,654,010		JOHNSON et al.	08-05-1997	
	AP	5,688,666		BASS et al.	11-18-1997	
	AQ	5,696,089		FELIX et al.	12-09-1997	
	AR	5,712,380		KENDALL et al.	01-27-1998	
	AS	5,721,250		MORRIELLO et al.	02-24-1998	
	AT	5,721,251		CHEN et al.	02-24-1998	
	AU	5,723,616		HOUGHTON et al.	03-03-1998	
	AV	5,726,307		SCHOEN et al.	03-10-1998	
	AW	5,726,319		LIN et al.	03-10-1998	
	AX	5,731,317		LU et al.	03-24-1998	
	AY	5,767,085		JOHANSEN et al.	06-16-1998	
	AZ	5,767,118		NARGUND et al.	06-16-1998	
	BA	5,767,124		DRAPER et al.	06-16-1998	
	BB	5,773,441		HIPSKIND et al.	06-30-1998	
	BC	5,776,901		BOWERS et al.	07-07-1998	
	BD	5,777,112		NARGUND et al.	07-07-1998	
	BE	5,792,747		SCHALLY et al.	08-11-1998	
	BF	5,795,957		DEGHENGHI et al.	08-18-1998	
	BG	5,798,337		SOMERS et al.	08-25-1998	
	BH	5,804,578		CHAKRAVARTY et al.	09-08-1998	
	BI	5,807,985		DEGHENGHI et al.	09-15-1998	
	BJ	5,830,433		DEAN et al.	11-03-1998	

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2

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Examiner Name	
Attorney Docket Number	TORRES=1B

**U.S. PATENT DOCUMENTS**

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		Number	Kind Code <sup>2</sup> (if known)			
SP	BK	5,834,598		LOWMAN et al.	11-10-1998	
	BL	5,843,453		HOLDER et al.	12-01-1998	
	BM	5,846,936		FELIX et al.	12-08-1998	
	BN	5,847,066		COY et al.	12-08-1998	
	BO	5,849,700		SØRENSEN et al.	12-15-1998	
	BP	5,849,704		SØRENSEN et al.	12-15-1998	
	BQ	5,849,535		CUNNINGHAM et al.	12-15-1998	
	BR	5,851,992		SØRENSEN	12-22-1998	
	BS	5,597,797		CLARK	01-1997	
SP	BT	5,137,872		SEELY et al.	08-1992	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>3</sup>	Number				
SP	BU	EPO	0075444B1	DE BOER et al.	03-30-1983		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
SP	BU	CARR et al., 5 <sup>th</sup> Conference on Retroviruses and Opportunistic Infections "A syndrome of peripheral lipodystrophy (LD), hyperlipidemia and insulin resistance due to HIV protease inhibitors (PI's)", Chicago, IL, Page 410 (February 1-5, 1998)	
	BV	MULLIGAN et al., 5 <sup>th</sup> Conference on Retroviruses and Opportunistic Infections "Evidence of unique metabolic effects of protease inhibitors", Chicago, IL, Page 414 (February 1-5, 1998)	
	BW	KERULY et al., 5 <sup>th</sup> Conference on Retroviruses and Opportunistic Infections "Diabetes and hyperglycemia in patients receiving protease inhibitors", Chicago, IL, Page 415 (February 1-5, 1998)	
	BX	DONG et al., 5 <sup>th</sup> Conference on Retroviruses and Opportunistic Infections "Diabetes and use of protease inhibitors", Chicago, IL, Page 416 (February 1-5, 1998)	
	BY	LO et al., "Buffalo hump" in men with HIV-1 infection, <u>The Lancet</u> , 351:867-870 (March 21, 1998)	
	BZ	MILLER et al., "Visceral abdominal-fat accumulation associated with use of indinavir", <u>The Lancet</u> , 351:871-875 (March 21, 1998)	
SP	CA	VIRABEN et al., "Indinavir-associated lipodystrophy", <u>AIDS</u> , 12:F37-F39 (1998)	

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		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	TORRES=1B
Sheet	3	of	8

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SP	CB	ADELMAN et al., "In vitro deletional mutagenesis for bacterial production of the 20,000-Dalton form of human pituitary growth hormone", <u>DNA</u> , 2:183-193 (1983)	
	CC	ALBERTSSON-WIKLAND et al., "Daily subcutaneous administration of human growth hormone in growth hormone deficient children", <u>Acta Poediatr Scand</u> , 75:89-97 (1986)	
	CD	BECKER et al., "Chemical, physical, and biological characterization of a dimeric form of biosynthetic human growth hormone", <u>Biotechnology and Applied Biochemistry</u> , 9:478-487 (1987)	
	CE	BEWLEY et al., "The chemistry of human pituitary growth hormone", <u>Adv. Enzymol. Related Areas</u> , 42:73-166 (1975)	
	CF	DENOTO et al., "Human growth hormone DNA sequence and mRNA structure: possible alternative splicing", <u>Nucleic Acids Research</u> , 9:3718-3731 (1981)	
	CG	HENDRICKS et al., "Plasma clearance of intravenously administered pituitary human growth hormone: gel filtration studies of heterogeneous components", <u>Journal of Clinical Endocrinology and Metabolism</u> , 60:864-867 (1985)	
	CH	JØRGENSEN et al., "Serum profiles and short-term metabolic effect of pituitary and authentic biosynthetic human growth hormone in man a double-blind cross-over study", <u>Acta Endocrinologica (Copenh)</u> , 116:381-386 (1987)	
	CI	JØRGENSEN et al., "Pharmacokinetics of biosynthetic and pituitary human growth hormones in rats", <u>Pharmacology &amp; Toxicology</u> , 63:129-134 (1988)	
	CJ	LEWIS et al., "An interchain disulfide dimmer of human growth hormone", <u>The Journal of Biological Chemistry</u> , 252:3697-3702 (1977)	
	CK	LEWIS et al., "Enhancement of the hyperglycemic activity of human growth hormone by enzymic modification", <u>Endo</u> , 101:1587-1603 (1977)	
	CL	LEWIS et al., "Human Growth hormone: additional members of the complex", <u>Endo</u> , 104:1256-1265 (1979)	
	CM	LEWIS et al., "Altered proteolytic cleavage of human growth hormone as a result of deamidation", <u>The Journal Of Biological Chemistry</u> , 256:11645-11650 (1981)	
SP	CN	HO et al., "Indinavir-associated facial lipodystrophy in HIV-infected patients", <u>AIDS Patient Care and STDs</u> , 13:11-16 (1999)	

Examiner Signature	<i>Shamir Bly</i>	Date Considered	11/14/95
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Sheet 4

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First Named Inventor	Ramon TORRES
Group Art Unit	
Examiner Name	
Attorney Docket Number	TORRES-1B

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SP	CO	KOSMISKI et al., "An increase in abdominal girth on protease inhibitor therapy is associated with visceral obesity and metabolic disturbances that closely resemble syndrome", 1 <sup>st</sup> International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV, 49-55 (1999)	
	CP	HENRY et al., "Atorvastatin and gemfibrozil for protease-inhibitor-related lipid abnormalities", <u>The Lancet</u> , 352:1031-1035 (1998)	
	CQ	ENGELSON et al., "Altered body fat distribution in HIV infection: regional body composition measurements by whole body MRI and DXA scans", 12 <sup>th</sup> World AIDS Conference Geneva, 471-471 (June 28-July 3 1998)	
	CR	HENRY et al., "Severe premature coronary artery disease with protease inhibitors", <u>The Lancet</u> , 351:1328 (1998)	
	CS	CARR et al., "Pathogenesis of HIV-1-proteases inhibitor-associated peripheral lipodystrophy, hyperlipidaemia, and insulin resistance", <u>The Lancet</u> , 351:1881-1883 (1998)	
	CT	CARR et al., "A syndrome of peripheral lipodystrophy, hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors", <u>AIDS</u> , F51-F58 (1998)	
	CV	BRINKMAN et al., "The first international workshop on adverse drug reactions and lipodystrophy in HIV session 4: related syndromes mitochondrial toxicity of nucleosides" <u>The Body: An AIDS and HIV Information Resource</u> , Abstract No. 9 (1999)	
	CW	ABSTRACT - TORRES et al., "The effect of recombinant human growth hormone on protease-inhibitor-associated fat maldistribution syndrome", 675	
	CX	ABSTRACT - VIARD et al., "Lipodystrophic syndromes in a cohort of HIV-1-infected patients receiving HAART with a protease inhibitor", Abstract No. 026	
	CY	WANKE et al., "Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV", <u>AIDS</u> , 2099-2103 (1999)	
	CZ	ABSTRACT 031 - RUIZ et al., "A multicentre, randomized, open-label, comparative trial of the clinical, immunological and virological benefit of switching the PI by nevirapine in HAART-experienced patients suffering lipodystrophy", 35	
	DA	ABSTRACT 068 - ROZENBAUM et al., "Prospective follow-up of a PI substitution for efavirenz in patients with HIV-related lipodystrophy syndrome"	
SP	DB	ABSTRACT 054 - MOLYLE et al., "Changes in visceral adipose tissue and blood lipids in persons reporting fat redistribution syndrome switched from PI therapy to efavirenz"	

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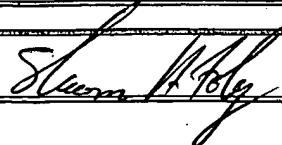
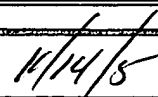
Application Number	NOT YET ASSIGNED
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First Named Inventor	Ramon TORRES
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Sheet 5

of 8

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

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SP	DC	MILLER et al., "Visceral abdominal-fat accumulation associated with use of Indinavir", <u>The Lancet</u> , 351:871-875 (1998)	
	DD	ABSTRACT 042 - MILANO et al., "Two case reports of unusual lipomatous growths associated with combination antiretroviral therapy"	
	DE	ABSTRACT 038 - MAGGI et al., "Precocious lesions of the carotid vessels in HIV-1-infected patients treated with protease inhibitors"	
	DF	ABSTRACT 018 - MERCIÉ et al., "Case report of lipodystrophy observations in patients naïve of protease inhibitor treatment, anquitaine cohort"	
	DG	KRENTZ et al., "Anthropometric, metabolic, and immunological effects of recombinant human growth hormone in AIDS and AIDS-related complex", <u>Journal of Acquired Immune Deficiency Syndromes</u> , 6(3):245-251 (1993)	
	DH	ENGELSON et al., "Fat distribution in HIV-infected patients reporting truncal enlargement quantified by whole-body magnetic resonance imaging" <sup>1,3</sup> , <u>Am J Clin Nutr</u> , 69:1162-1169 (1999)	
	DI	BECKER et al., "A nondiabetogenic derivative of human growth hormone", 342:108	
	DJ	BJORNTORP et al., "Review the regulation of adipose tissue distribution in humans", <u>International Journal of Obesity</u> , 20:291-302 (1996)	
	DK	CARR et al., "Diagnosis, prediction, and natural course of HIV-1 protease-inhibitor-associated lipodystrophy, hyperlipidaemia, and diabetes mellitus: a cohort study", <u>The Lancet</u> , 353:2093-2099 (1999)	
	DL	CHEN et al., "The human growth hormone locus: nucleotide sequence, biology, and evolution", <u>Genomics</u> , 4:479-497 (1989)	
	DM	ABSTRACT 006 - ENGELSON et al., "Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interim analysis", <u>Antiviral Therapy</u> , 4(Supplement 2):19 (1999)	
	DN	HSIUNG et al., "Use of bacteriocin release protein in <i>E. Coli</i> for excretion of human growth hormone into the culture medium", <u>Bio/technology</u> 7:267-271 (1989)	
SP	DO	JONES et al., "Crystallization of authentic recombinant human growth hormone", <u>Bio/technology</u> , 5:499-500 (1987)	

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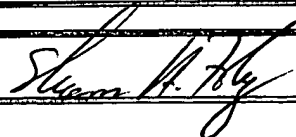
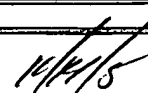
Sheet 6

of 8

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First Named Inventor	Ramon TORRES
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SP	DP	LEWIS et al., "A naturally occurring structural variant of human growth hormone", <u>The Journal of Biological Chemistry</u> , 253:2679-2687 (1978)	
	DQ	LEWIS et al., "Altered proteolytic cleavage of human growth hormone as a result of deamidation", <u>The Journal of Biological Chemistry</u> , 11645-11650 (1981)	
	DR	ZUREK et al., "Human growth hormone: complementary DNA cloning and expression in bacteria", <u>Science</u> 205:602-607 (1979)	
	DS	ABSTRACT P145 - MAUSS et al., "Successful treatment of PI-induced visceral abdominal-fat accumulation with R-human growth hormon"	
	DT	MOCROFT et al., "Changes in AIDS-defining illnesses in a London clinic, 1987-1998", <u>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</u> , 21:401412 (1999)	
	DU	MOORE et al., "Equivalent potency and pharmacokinetics of recombinant human growth hormones with or without an N-terminal methionine", <u>Endocrinology</u> , 122:2920-2926 (1988)	
	DV	WINDISCH et al., "Recombinant human growth hormone for AIDS-associated wasting", <u>The Annals of Pharmacotherapy</u> , 32:437-445 (1998)	
	DW	KOTLER et al., "Studies of body composition and fat distribution in HIV-infected and control subjects", <u>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</u> , 20:228-237 (1999)	
	DX	PINEDA, "Predictable upwelling and the shoreward transport of planktonic larvae by internal Tidal Bores", <u>Science</u> , 548	
	DY	CARR et al., "Pathogenesis of HIV-1-protease inhibitor-associated peripheral lipodystrophy, hyperlipidaemia, and insulin resistance" <u>The Lancet</u> , 351:1881-1883 (1998)	
	DZ	CARR et al., "Fast track a syndrome of peripheral lipodystrophy, hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors", <u>AIDS</u> , 12:F51-F58 (1998)	
	EA	MICHAELS et al., "Differences in the incidence rates of opportunistic processes before and after the availability of protease inhibitors", <u>5<sup>th</sup> Conference on Retroviruses and Opportunistic Infections</u> , (February 1-5, 1998)	
	EB	DONG et al., "Diabetes and use of protease inhibitors", <u>12<sup>th</sup> World AIDS Conference Geneva</u> , (June 28 - July 3 1998)	

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SP	EC	ABSTRACT No. PB0895 - MUURAHAINEN et al., "Detection of occult wasting by BIA technology", <u>International Conference AIDS</u> , 10(2)220 (Aug. 7-12 1994)	
	ED	VIRABEN et al., "Fast Track indinavir-associated lipodystrophy", <u>AIDS</u> , 12::F37-F39 (1998)	
	EE	LEWIS et al., "The 20,000-Dalton variant of human growth hormone' location of the amino acid deletions", <u>Biochemical and Biophysical Research Communications</u> , 92:511-516 (1980)	
	EF	BJORNTORP et al., "Abdominal obesity and the development of noninsulin-dependent diabetes mellitus", <u>Diabetes/Metabolism Reviews</u> , 4:615-622 (1998)	
	EG	JONES et al., "Crystallization of authentic recombinant human growth hormone", <u>Biotechnology</u> , 5:499-500 (1987)	
	EH	MARTIAL et al., "Human growth hormone: complementary DNA cloning and expression in bacteria", <u>Science</u> , 602-607 (1979)	
	EI	BEWLEY et al., "Sequence comparison of human pituitary growth hormone, human chorionic somatomammotropin, and ovine pituitary growth and lactogenic hormones", <u>Int. J. Peptide Protein Res.</u> , 4:281-287 (1972)	
	EJ	ABSTRACT 010 - CHENG, "Lipodystrophy in HIV: a community perspective" (1999)	
	EK	CUNNINGHAM et al., "Dimerization of human growth hormone by Zinc", <u>Science</u> , 253:544-548 (1991)	
	EL	ABSTRACT 006 - ENGELSON et al., "Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interim analysis" (1999)	
	EM	ABSTRACT 336*/32173 - KOTLER et al., "Alterations in body fat distribution in HIV-infected men and women" <u>12 World AIDS Conference Geneva</u> (June 28-July 3 1998)	
	EN	ABSTRACT 022 - MUURAHAINEN et al., "The SALSA (self-ascertained lipodystrophy syndrome assessment) cohort: abnormalities in cases compared to controls" (1999)	
	EO	ABSTRACT 063 - MUURAHAINEN et al., "Abnormalities in HIV-associated lipodystrophy syndrome that vary by weight status" (1999)	
SP	EP	ABSTRACT 177*/12373 - DONG et al., "Changes in body habitus in HIV(+) women after initiation of protease inhibitor therapy" (1998)	

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
SR	EQ	Mayo, <u>Mol. Endocrinology</u> , 6:1734-1744 (1992)	
	ER	DENOTO et al., <u>Nucleic Acids Research</u> , 9(15)3719-3730 (1991)	
	ES	KRENTZ et al., Anthropometric, metabolic, and immunological effects of recombinant growth hormone in AIDS and AIDS-related complex, <u>J. Acquir Immune Defic Syndr.</u> , 6(3)245-251 (1993)	
	ET	WINDISCH et al., Recombinant human growth hormone for AIDS-associated wasting, <u>Ann Pharmacother</u> , 32(4):437-45 (1998)	
	EU	JAMES et al., Successful treatment of "buffalo hump" with growth hormone* AIDS treatment news, 298:5-6 (1998)	
SR	EV	MAUS et al., Successful treatment of PI-induced visceral abdominal fat accumulation with R-human growth hormone, <u>AIDS</u> , 12 Sup 4:145 (1998)	

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